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DUPLICATE OF THE ORIGINAL

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 358]

[DOCKET NO. 78N-0065]

SKIN BLEACHING DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

ACCEPTANCE OF DATA AND INFORMATION INTO THE ADMINISTRATIVE RECORD

45 FR 18404
3-21-80

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice advises that the Food and Drug Administration (FDA) reopened the administrative record for over-the-counter (OTC) skin bleaching drug products to allow for consideration of data and information that had been filed with the Hearing Clerk, Food and Drug Administration, after the date that the administrative record officially closed.

ADDRESS: Data and information are on public file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

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FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson,
Bureau of Drugs (HFD-510),
Food and Drug Administration,
Department of Health, Education, and Welfare,
5600 Fishers Lane,
Rockville, MD 20857,
301-443-4960.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record. Under § 330.10(a)(10)(i) (21 CFR 330.10(a)(10)(i)) the administrative record closes with respect to the submission of new data and information at the end of the comment period following publication of the panel report in the FEDERAL REGISTER. The comment period for OTC skin bleaching drug products closed on February 1, 1979, and the reply comment period closed on March 5, 1979. The procedural regulations for OTC drugs, § 330.10(a)(10)(ii) (21 CFR 330.10(a)(10)(ii)), provide that after the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record. In some cases, persons have not submitted such petitions; rather they have submitted new data and information to the Hearing Clerk as comments on the panel report. In the interest of expediting the

OTC drug review and because FDA wishes to consider all pertinent data and information that have been submitted to the Hearing Clerk, Food and Drug Administration, prior to the date of publication of this notice, the agency has concluded that the new data and information, whether or not properly filed, should be available to the agency in developing a tentative final order. By this notice, FDA announces that it is treating these submissions, received after the administrative record has closed, as petitions to reopen the administrative record, and is granting the petitions by allowing new data and information contained therein to be included in the administrative record for OTC skin bleaching drug products. This notice serves to inform interested persons of the existence of these data and information and their availability for review at the office of the Hearing Clerk, Food and Drug Administration. Comments on these data and information will not be accepted at this time. However, interested persons will have an opportunity to submit comments and additional new data and information at times to be specified in future FEDERAL REGISTER notices.

Dated: March 12, 1980.

MAR 12 1980

William F. Randolph

William F. Randolph
Acting Associate Commissioner for
Regulatory Affairs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Robin M Spencer